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September 22, 2014

VIA ECF

Honorable Naomi Reice Buchwald
United States District Judge
Daniel Patrick Moynihan Courthouse
500 Pearl Street
New York, NY 10007-1312

Re: *In re Intercept Pharmaceuticals, Inc. Sec. Litig.*
No. 1:14-cv-01123-NRB

Dear Judge Buchwald:

In accordance with Rule 2(E)(1) of the Court's Individual Practices, counsel for Lead Plaintiff George Burton respectfully submits this letter addressing the substantive arguments raised in Plaintiff's Opposition to Defendants' Motion to Dismiss the Consolidated Complaint.[1]

This is a straightforward case of securities fraud. Intercept is a pharmaceutical company that, in its first 12 years of existence, had not brought a single product to market. As of January 2014, Intercept had only developed a single drug, OCA. OCA was in the clinical trial stage, and the primary trial for the drug, the FLINT trial, was being run by National Institute of Diabetes and Digestive and Kidney Diseases ("NIDDK"). On January 6, 2014, the NIDDK informed Defendants that the FLINT trial was being halted because OCA had crossed an efficacy boundary and the agency found "significant lipid abnormalities" in patients taking OCA compared to those on placebo. Defendants promptly told the NIDDK that they would inform investors that "the treatment phase of the study has been terminated on the basis of efficacy and that lipid abnormalities have been observed." Three days later, on January 9, 2014, Defendants told investors the positive news about the NIDDK's finding of efficacy, but failed to disclose the negative news about the lipid abnormalities or the role that safety risk played in the NIDDK's decision to halt the FLINT trial. In response to Defendants' misleading statements and omissions, Intercept's stock price increased 515% and closed above $445 per share on January 10, 2014. Less than 36 hours after Defendants issued their incomplete and inaccurate statements, the NIDDK took what it described as the unusual step of issuing its own statement, disclosing the true facts about OCA and the finding of "significant lipid abnormalities." As a result of that disclosure, Intercept's stock price plunged more than $191 per share, significantly damaging Plaintiff and other investors.

[1] Defendants are Intercept Pharmaceuticals, Inc. ("Intercept" or the "Company"), CEO Dr. Mark Pruzanski and Chief Medical Officer Dr. David Shapiro (collectively, "Defendants").

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Defendants concede that Plaintiff's Consolidated Complaint for Violations of the Federal Securities Laws (Dkt. No. 26) (the "Complaint") adequately pleads (i) the misrepresentation and omission of material facts on January 9, 2014; (ii) Defendants' knowledge of the facts about OCA and the FLINT trial that rendered their statements false and misleading when made; (iii) Plaintiff's purchase of Intercept securities during the class period; (iv) reliance upon Defendants' misrepresentations and omissions; (v) economic loss; and (vi) loss causation. Despite conceding that they knew, but failed to disclose, the true facts about OCA and the FLINT trial, Defendants argue that the Complaint does not plead a "strong inference" of scienter because it does not allege Defendants personally believed the undisclosed facts were material.

Defendants' argument ignores the Second Circuit standard for pleading scienter. In this Circuit, a strong inference of scienter is plead when a plaintiff has "specifically alleged defendants' knowledge of facts or access to information contradicting their public statements. Under such circumstances, defendants knew or, more importantly, should have known that they were misrepresenting material facts related to the corporation." *Novak v. Kasaks*, 216 F.3d 300, 308 (2d Cir. 2000). Defendants cannot escape liability simply by claiming that they did not believe the facts they misstated and omitted were immaterial. As Judge Swain recognized in *In re Pfizer Inc. Sec. Litig.*, 584 F. Supp. 2d 621, 639 (S.D.N.Y. 2008), "[h]aving established the sufficiency of Plaintiffs' allegations as to materiality as well as the Individual Defendants' knowledge, the question of scienter is implicitly resolved."

Relying on the Second Circuit's *Carter-Wallace* decisions and their progeny, Defendants' argument is premised on the proposition that safety warnings about pharmaceutical products do not become material until they are "statistically significant" or "commercially significant." That proposition, however, in no longer good law. In *Matrixx Initiatives, Inc. v. Siracusano*, __U.S.__ 131 S. Ct. 1309, 1318 (2011), the Supreme Court specifically rejected Defendants' argument that risks associated with a pharmaceutical product could not be material unless those risks were statistically significant. *See, e.g.*, *In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 563 n.9 (S.D.N.Y. 2011) ("the Supreme Court recently rejected the bright-line rule expressed in *Carter-Wallace I* by holding that the mere absence of statistically significant evidence does not demonstrate a lack of materiality"). The Supreme Court also rejected the argument made here that Defendants could not have acted with scienter if they did not believe the risks associated with a drug were material. *Matrixx*, 131 S. Ct. at 1324 (defendants' "proposed bright-line rule requiring an allegation of statistical significance to establish a strong inference of scienter is just as flawed as [their] approach to materiality").

Plaintiff's allegations leave no doubt that the NIDDK's finding of significant lipid abnormalities and the role that finding played in the halting of the FLINT trial are material. OCA was Intercept's lone product, and approval of the drug was expected to result in billions of dollars in annual sales for Intercept. Defendants themselves told investors that the results of the FLINT trial would be "pivotal" to Intercept's goal of gaining FDA approval of OCA. Indeed,

when the NIDDK first informed Defendants of the finding of significant lipid abnormalities, Defendants acknowledged that it would have to be disclosed to investors. After Defendants failed to disclose the truth about the lipid abnormalities, the NIDDK took the unusual step of releasing its own statement, revealing the finding of significant lipid abnormalities with OCA in the FLINT trial. Defendants themselves, in trying to stop the NIDDK from issuing the release, acknowledged that "[t]he lipid information is specific and I think will cause issues" with investors. The NIDDK's disclosure did cause issues with investors and the reaction of the market to the disclosure of the truth about OCA and the FLINT trial further evidences materiality: Intercept's stock price plunged $190.71 per share, a 43% decline, in the immediate aftermath of the NIDDK's disclosure of the facts Defendants misstated and omitted.

Defendants' arguments to the contrary are not even credible. Defendants repeatedly claim that the NIDDK "approved" their January 9, 2014 statements. In fact, the NIDDK specifically told Defendants that the contents of Intercept's public statements were Defendants' responsibility and reminded them of the role the safety risks with OCA played in the decision to halt the FLINT trial. Defendants next argue that they "had no actual data" to review regarding the FLINT trial and lipid abnormalities. But, Defendants had the specific finding of the NIDDK, the agency that was conducting the FLINT trial and the agency that was charged with interpreting trial data. And, of course, Defendants did not wait to review the "actual data" from the trial before rushing to tell investors the good news about the NIDDK's efficacy findings.

Defendants also argue that the finding of lipid abnormalities was already known to the public. There is no evidence, let alone allegations or information that could be considered on a motion to dismiss, that this is true. The lone disclosure Defendants point to actually claims "[t]here was no clear, concerning safety signals" associated with OCA and is about an "exploratory study" unrelated to the NIDDK or the FLINT trial. Finally, Defendants claim that they cannot be liable for securities fraud because they "promised" to release the full results of the FLINT trial at some later date. The securities laws, however, require that "upon choosing to speak, one must speak truthfully about material issues" and has "a duty to be both accurate and complete." *Caiola v. Citibank, N.A.*, 295 F.3d 312, 331 (2d Cir. 2002). Having elected to disclose the good news about OCA and the FLINT trial, Defendants were obligated to disclose the bad news as well.

In accordance with Fed. R. Civ. P. 9(b) and the Private Securities Litigation Reform Act of 1995, Plaintiff has identified Defendants' material misstatements and omissions, alleged why those statements were false when made and set forth unrefuted evidence that, at the time they spoke, Defendants knew the very facts about OCA and the FLINT trial that rendered their statements false and misleading. No more is required and Defendants' motion to dismiss should be denied in its entirety.

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Respectfully submitted,

TOR GRONBORG

TG:mm
cc: All Counsel (via ECF)